HFI-35 9/1/00

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-93

August 29, 2000

Elizabeth C. Metcalf, Owner
Rock Landing Seafood
U. S. Highway 98
12 Rock Landing Road
Panacea, FL 32346

Dear Mrs. Metcalf:

We inspected your firm, located at 12 Rock Landing Road, Panacea, FL on November 16, 1999 and found serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause the fresh crabmeat produced in this facility to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The deviations were as follows:

> You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your HACCP plan for fresh crabmeat does not list the food safety hazard(s) of pathogen survival, growth and toxin formation.

The following deviations reflect our review of your revised HACCP plan for fresh crabmeat that you hand-drafted during the FDA inspection on November 16, 1999, and had not yet implemented:

> You must have a written HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh crabmeat fails to list a maximum product temperature at the picking/packing critical control point. Therefore, the listed critical limit for maximum product exposure time (i.e., "No more than 3 1/2 hrs. Cumulative Time 2 hrs") is inadequate to control significant hazards of pathogen growth and toxin formation that may occur at this step in the process. Also, it is confusing why you have elected to identify apparently two exposure time periods at this critical control point.

You must have a written HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh crabmeat fails to list how the cook time and temperature will be monitored at the cooking critical control point to control the pathogen survival hazard. The monitoring procedure listed states that the cook time, temperature, and pressure will be monitored, but the only monitoring instrument listed in the plan is a pressure gauge. Your HAACP plan also fails to state how the product temperature will be monitored at the picking and packing critical control point to control the pathogen growth and toxin formation hazards.

You must implement monitoring procedures listed in your written HACCP plan to comply with 21 CFR 123.6(b). However, the HACCP plan for fresh crabmeat had not been implemented for monitoring the cooking critical control point for cook time and temperature, and the finished product storage critical control point for storage temperature. Also, monitoring at the picking/packing critical control point is inconsistent with the HACCP plan for product exposure time to control pathogen growth and toxin formation. The HACCP plan states that the picking/packing critical control point will be monitored to assure that the time of product exposure unrefrigerated is one hour. Yet the critical limit for this critical control point is "no more than 3 1/2 hours"..

You must implement the record keeping system listed in your written HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the cooking critical control point and finished product storage critical control point to control pathogen growth and toxin formation.

You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor exclusion of pests and prevention of cross contamination with sufficient frequency to ensure control as evidenced by the live flies observed in the processing room and storage of cooked crabs against the wall of the cooler.

You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that are not adequate, as they do not cover all of the required sanitation conditions and practices and they are not dated.

Since you chose to include corrective actions in your HACCP plan, your planned corrective action(s) must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for fresh crabmeat does not address the disposition of adulterated product when re-cooking would not be appropriate and the product is segregated at the cooked crab cooler critical control point. Also, you did not specify the circumstances when re-cooking would be appropriate. In addition, the corrective action plan to "re-ice" at the finished product storage critical control point does not specify when re-icing would not be appropriate or, vice versa, the condition when re-icing only is appropriate.

We received a response from you dated January 7, 2000 to the List of Observations, FD-483, issued to you at the conclusion of the November 16, 1999 inspection. However our review of this response found that it did not adequately address all of the serious deviations noted in the inspection and there was no copy of the revised HACCP plan or examples of completed monitoring or sanitation control records attached.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a copy of your HACCP plan, monitoring records and sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

Edward R. Singleton for

Emma R. Singleton
Director, Florida District